

**510(k) Summary****Date:**

24 January 2011

**Sponsor:****Ulrich GmbH & Co. KG**Buchbrunnenweg 12  
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Germany

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JAN 25 2011

**Contact Person:**Hans Stover  
Ulrich Medical USA, Inc.  
754 Spirit 40 Park Drive  
Chesterfield, MO 63005  
Phone: (636) 519-0268**Proposed Trade Name:**

flamenco™ spinal fixation system

**Device Classification**

Class II

**Classification Name:**

Pedicle screw spinal system &amp; Spinal interlaminar fixation orthosis

**Regulation:**

888.3070 &amp; 888.3050

**Device Product Code:**

MNI/MNH &amp; KWP

**Device Description:**

The flamenco™ consists of rods, monoaxial and polyaxial pedicle screws, hooks and transverse connectors with locking set screws. The components are available in various sizes to accommodate differing patient anatomy. Rods are available in one diameter and a variety of lengths. Monoaxial and polyaxial screws are available in a variety of diameter-length combinations. Hooks are offered in a variety of shapes and sizes.

**Intended Use:**

The flamenco™ is a spinal fixation system intended to provide immobilization and stabilization of thoracic, lumbar, and sacral spinal segments as an adjunct to fusion.

When used as posterior, pedicle screw fixation, the system is intended for the treatment of severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients. In addition, when used as a pedicle screw fixation system in the non-cervical posterior spine (T1 to S2), the system is intended for the treatment of the following acute and chronic instabilities or deformities: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, spinal stenosis, scoliosis, kyphosis, lordosis, spinal tumor, pseudarthrosis and failed previous fusion in skeletally mature patients.

When used as a posterior, non-cervical, hook and/or sacral/iliac fixation system (i.e., non-pedicle screw), the flamenco™ is intended for the treatment of the following acute and chronic instabilities or deformities: degenerative disc disease (as

conformed by patient history and radiographic studies), spondylolisthesis, fracture, dislocation, scoliosis, kyphosis, lordosis, spinal stenosis, spinal tumor, pseudarthrosis and failed previous fusion.

**Materials:**

The flamenco™ components are manufactured from titanium alloy (Ti-6Al-4V) as described by ISO 5832-3 / ASTM F136.

**Predicate Devices:**

CD HORIZON® (K031655/K041460)

Moss Miami (K992168/K022623)

Synergy VLS (K950099/K974749)

Optima™ (K024096/K031585/K051971)

Diamondback™ (K100377)

**Technological Characteristics:**

The flamenco™ possesses the same technological characteristics as the predicate devices. These include

- basic design (rod-based fixation system having monoaxial and polyaxial pedicle screws and various hook shapes and sizes),
- material (titanium alloy),
- sizes (rod and screw sizes are encompassed by those offered by the predicate systems) and
- intended use (as described above).

The fundamental scientific technology of the flamenco™ is the same as previously cleared devices.

**Performance Data:**

Static compression bending and torsion, and dynamic compression bending of the worst case flamenco™ construct was performed according to ASTM F1717. The mechanical test results demonstrated that flamenco™ performs as well as or better than the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

JAN 25 2011

ulrich GmbH & Co. KG  
% ulrich medical USA, Inc.  
Mr. Hans Stover  
754 Spirit 40 Park Drive  
Chesterfield, Missouri 63005

Re: K102853

Trade/Device Name: flamenco™ Spinal Fixation System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: Class II  
Product Code: MNH, MNI, KWP  
Dated: December 09, 2010  
Received: December 10, 2010

Dear Mr. Stover:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

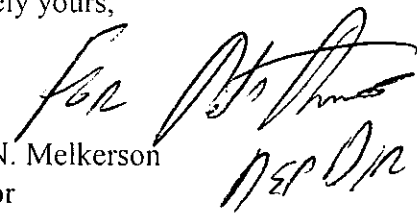
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

  
Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
And Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## **Indications for Use Statement**

510(k) Number: K102853

Device Name: **flamenco™ spinal fixation system**

Indications for Use:

The flamenco™ is a spinal fixation system intended to provide immobilization and stabilization of thoracic, lumbar, and sacral spinal segments as an adjunct to fusion.

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Prescription Use   X  

AND/OR

Over-the-Counter Use           

(21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)

Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K102853